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10/573,513	03/27/2006	David R. Whitlock	D0460-7010US	3543

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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01/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/573,513	Applicant(s) WHITLOCK, DAVID R.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/20.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/7/07, 11/6/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-14 as originally filed are currently pending.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-8, in the reply filed on 10/20/08 is acknowledged. The traversal is on the ground(s) that examining all three Groups would not be burdensome to the examiner because the inventions are allegedly not "independent and distinct" as required in M.P.E.P. § 802.1 (Reply, pages 5-6). Chapter 800, however, is limited to a discussion of the subject of restriction and double patenting under Title 35 of the United States Code and Title 37 of the Code of Federal Regulations as it relates to national applications filed under 35 U.S.C. 111(a). The discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules as it is applied as an International Searching Authority, International Preliminary Examining Authority, and in applications entering the National Stage under 35 U.S.C. 371 as a Designated or Elected Office in the U.S. Patent and Trademark Office is covered in M.P.E.P. §1850 and is dictated by PCT Rules 13.1 and 13.2. See M.P.E.P. §801. Burden is not a consideration in a finding of lack of inventive unity; rather, according to M.P.E.P. §1850, the only consideration is whether the inventions share a special technical feature. Applicant has provided no convincing argument that the inventions share such a feature. The requirement is still deemed proper and is therefore made FINAL.

Applicant's election with traverse of the species "a subject who is at risk of developing obesity" and "*Nitrosomonas*" in the reply filed on 10/20/08 is acknowledged.

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The traversal is on the ground(s) that the species are not independent and distinct (Reply, pages 6-8, and accompanying documents). This is not found persuasive because once again, applicant has provided arguments that are not relevant to cases filed under 35 U.S.C. § 371. As discussed in the restriction requirement, the only consideration is whether the species are art-accepted equivalents for each other, not whether they are "independent and distinct." Applicant has made no convincing argument and provided no evidence that the skilled artisan would have considered the species discussed in the restriction requirement to be art-accepted equivalents for each other. The requirement is still deemed proper and is therefore made FINAL.

Claims 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/20/08.

Examination on the merits will commence at this time on claims 1-8 ONLY, to the extent they read on the elected species where applicable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The claims (in light of the species election) are drawn to treating a subject at risk of developing obesity comprising identifying such a subject and positioning ammonia-oxidizing bacteria (AOB) "in close proximity" to the subject. In some dependent claims, the AOB and amount to be applied is pointed out. In some dependent claims, the manner of application is further described.

Several aspects of the claims warrant discussion as it pertains to enablement. First, as discussed in the indefiniteness and art rejections below, the claims do not require that the contacting step have any particular effect on the subject being treated. However, in the interest of compact prosecution, and in light of the disclosure (see page 2, line 30, through page 3, line 20; page 33, line 1, through page 34, line 24; page 81, lines 1-16; and page 95, line 30, through page 96, line 24), the claims have been interpreted for this ground of rejection only as requiring that obesity be prevented.

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Obesity is a persistent problem in the art. Johnson et al. (2006, *Journal of the American Dietetic Association* 106: 97-102; reference U), published years after the instant application, teaches that obesity is a complex condition with many possible causes, including gender, race, socioeconomic condition, maternal contribution during gestation, learned behaviors, environmental factors, and age of onset of puberty (pages 97-100). Johnson concludes that even after the instant filing, additional research is necessary to identify ways to prevent obesity in all individuals, because there are so many different life periods at which intervention is necessary (page 100, column 2).

Methods for treatment of obesity were known in the art at the time of filing; these methods include special diets and weight reduction programs, e.g. exercise (Bojrab; U.S. Patent 6,641,808; reference A; at column 5, lines 34-56). Indeed, some probiotic bacteria have been shown to reduce body mass index when ingested orally (see Bojrab at column 9, lines 34-48). However, at the time of the invention, the art was silent as to the ability of any bacteria, administered in any way, to prevent obesity. Furthermore, there are no prior art teachings of topically applied bacteria of any kind preventing obesity. M.P.E.P. § 2164.03 reads, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The 'amount of guidance or direction' refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information

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needs to be explicitly stated in the specification. **In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling.** See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004)...In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required.” As the above discussion illustrates, the ability of topically applied bacteria of any kind, including AOB, to prevent obesity was unpredictable at the time of the invention, so treatment of such diseases must be considered “nascent,” and the amount of guidance required is relatively high.

When the state of the art is nascent, the examiner must turn to the guidance in the specification for guidance in carrying out the claimed invention. In this case, the working examples are limited to a single pilot experiment in which a composition allegedly comprising AOB was applied to the skin of a single individual (the inventor) and allowed to remain without being washed off for several years (see page 94, lines 15-18; and page 106, line 32). The working examples (see page 93, lines 25-33, and page 107, lines 1-12) do not clearly indicate that the composition applied in the working examples prevented obesity *per se*. It is noted that the inventor noted reduction in appetite and observed weight loss during the time the AOB was present (page 34, lines 20-24), but given the teachings of Johnson and Bojrab as to the complex nature of

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obesity, there is insufficient evidence to conclude that the application of AOB resulted in prevention of obesity, especially since the specification does not clearly indicate that after the weight loss, the inventor was not obese; all that is discussed is a weight loss.

The claimed method requires positioning AOB in close proximity to the subject, e.g. applying it to the skin ("surface") of the subject. However, the specification does not clearly indicate that the working examples include such an application. The specification indicates (page 94, lines 15-16; and page 107, lines 1-4) that soil was obtained and cultured in ammonia-containing media, but the specification does not appear to include any evidence that the contents of the composition applied to the scalp and body of the experimental subject contained any particular bacterial strain, much less the specific strains recited in claim 2. The specification indicates that the "strain" used in the examples "does not utilize urea directly, and does not have a nitrate reductase" (page 95, lines 5-6). However, this information on its own is inadequate to establish that the bacteria allegedly present in the composition applied to the subject's body in the working examples are any particular strain of AOB or even that they are AOB.

Regarding the requirement in claim 3 that an "effective amount" of bacteria be applied to the skin ("surface") of a subject, the specification provides inadequate guidance to determine this amount. In *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993), the 1983 application disclosed a vaccine against the RNA tumor virus known as Prague Avian Sarcoma Virus, a member of the Rous Associated Virus family. Using functional language, Wright claimed a vaccine "comprising an immunologically effective amount" of a viral expression product. *Id.*, at 1559, 27 USPQ2d at 1511.

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Rejected claims covered all RNA viruses as well as avian RNA viruses. The examiner provided a teaching that in 1988, a vaccine for another retrovirus (i.e., AIDS) remained an intractable problem. This evidence, along with evidence that the RNA viruses were a diverse and complicated genus, convinced the Federal Circuit that the invention was not enabled for either all retroviruses or even for avian retroviruses. The fact pattern is similar in this case, since Johnson and Bojrab indicate that preventing obesity is an unpredictable art, and the specification includes insufficient guidance for preventing obesity under any circumstances.

While a singular, narrow working embodiment cannot be a sole factor in determining enablement, its limited showing, in light of the unpredictable nature of the art and the lack of direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in using the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, in light of the species election, is drawn to a method of treating a subject at risk of developing obesity by positioning AOB in close proximity to that subject, but there is no requirement that the positioning step result in any particular effect. For

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example, the claim does not require that obesity is prevented in the subject. The steps of the method do not appear to be commensurate in scope with the preamble.

Clarification is required.

Claim 1 is drawn to a method of treating a subject that requires “positioning [AOB] in close proximity to the subject.” The method steps do not appear to be commensurate in scope with the preamble. In order to treat a subject, the subject is generally contacted with the active agent. Currently, there is no requirement that the AOB contact the subject or, indeed, be in the same building with the subject (since adjacent houses are reasonably considered to be “in close proximity”). Clarification is required.

Furthermore, while not elected species, there is a disconnect between the species “aging” and “retarding due to aging” in the preamble of claim 1 and the “identifying” step of claim 1. There is no provision for identifying a subject who has developed or is at risk for aging or retarding due to aging. Clarification is required.

Because claims 2-8 depend from indefinite claim 1 and do not clarify all of the points of confusion, it must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 2 is in improper Markush form; a Markush group should be in the form “a bacteria selected from the group consisting of A, B, and C”. Currently, it is not clear which species are included in the Markush group and which are not. The use of the phrase “the group consisting of any of” is queried as this is not standard Markush-type language. Clarification is required.

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Claim 3 requires applying bacteria "in an effective amount" to a surface of the subject being treated. The common phrase "an effective amount" may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an "effective amount of a compound of claim 1" without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected. See M.P.E.P. § 2173.05 (c) (III).

In this case, the specification does not provide any guidance for identifying a particular amount of any particular bacteria. At page 8, lines 3-14, the specification generally contemplates that any AOB can be used in the invention, but the working examples provide no guidance for identifying an effective amount of any of the recited bacteria for any purpose. At page 107, lines 1-12, of the as-filed specification, a process for producing "an enrichment culture of [AOB]" by culturing barnyard soil in ammonia-containing medium until the culture reached high levels of nitrite is disclosed. However, nowhere does the specification indicate that any of the bacteria recited in claim 2 are present in the composition applied at page 107, and the specification is also silent as to the amount of active agent applied. Given the enablement issues in this case (see above), it is not clear what amount of bacteria would constitute an "effective amount."

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Because claims 4-8 depend from indefinite claim 3 and do not clarify the point of confusion, it must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 5 requires applying bacteria to "skin, hair, or a combination thereof," but there is no requirement that the "subject" in claim 3 be a mammal or, indeed, an animal. Therefore, there is no antecedent basis for these limitations in claim 5. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hikuma et al. (1981, U.S. Patent 4,297,173; reference A).

Hikuma teaches a process including culturing *Nitrosomonas europaea* in a laboratory (Example 2 at column 7, lines 16-38). The *Nitrosomonas* of Hikuma is in close proximity to the laboratory workers carrying out the culturing in that the workers and the bacteria are in the same lab. Every individual is at some risk of developing obesity. As discussed above, there is not requirement that any particular outcome arise from the positioning step. The reference therefore anticipates the claims.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

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identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 3-8 of copending Application No. 10/332,933. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Instant claim 1 is drawn to a method of treating a subject who is at risk for obesity (i.e., any subject) by positioning AOB in close proximity to the subject; instant claim 3 requires applying the AOB to the surface of the subject such that they metabolize certain compounds. Claim 1 of the '933 application is drawn to a method of supplying nitric oxide to a subject (i.e., any subject) by applying AOB to the surface of the subject such that they metabolize certain compounds. Because the method steps are identical and the scope of the subject is identical (i.e., every individual) in both claim sets, the claims have identical scope. Instant claim 2 correlates with claim 4 of the '933 application. Instant claim 4 correlates with claim 3 of the '933 application. Instant claim 5 correlates with claim 5 of the '933 application. Instant claim 6 correlates with claim 6 of the '933 application. Instant claim 7 correlates with claim 7 of the '933 application. Instant claim 8 correlates with claim 8 of the '933 application.

No claims are allowed.

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Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651